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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

In re THORATEC CORP. SECURITIES LITIGATION This Document Relates to: ALL ACTIONS	No. C-04-03168 RMW ORDER GRANTING MOTION TO DISMISS CONSOLIDATED COMPLAINT **[Re: Docket No. 31]**

Defendants Thoratec Corporation ("Thoratec"), D. Keith Grossman ("Grossman"), M. Wayne Boylston ("Boylston"), and Jeffrey Nelson ("Nelson") (collectively "defendants") move to dismiss lead plaintiff Toby Craig's Consolidated Complaint ("Compl."). Plaintiff opposes the motion. The motion was heard on June 17, 2005. The court has read the moving and responding papers and heard the argument of counsel. For the reasons set forth below, the court grants defendants' motion to dismiss plaintiff's first and second claims for relief with leave to amend.

I. BACKGROUND[1]

This action, filed August 3, 2004, is brought on behalf of a proposed class of persons who purchased the publicly-traded securities of Thoratec between April 28, 2004 and June 29, 2004 ("class period"). Plaintiff's complaint alleges violations of section 10(b) of the Exchange Act, 15 U.S.C. §§ 78j(b), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5, by all defendants, and alleges violations of § 20(a) of the Exchange Act by individual defendants Grossman, Boylston, and Nelson. Plaintiff alleges that Thoratec securities were traded at artificially-inflated prices during the class period as a result of defendants' alleged actions, misrepresentations, and omissions, specifically that defendants (1) made false and misleading statements regarding expected sales and market prospects of a key Thoratec product, the HeartMate XVE; and (2) concealed adverse material facts about the HeartMate XVE.

Thoratec is a leading supplier of implantable and external circulatory support products, known as "ventricular assist devices" ("VADs"), for treating patients with congestive heart failure. Compl. ¶ 2. Some patients with congestive heart failure qualify for heart transplantation. As an interim measure while awaiting transplant, these patients may receive a left ventricular assist device ("LVAD") as a "bridge to transplant." *Id.* Other patients cannot qualify for heart transplantation because of a variety of factors such as unavailability of a transplant heart or medical unsuitability. Thoratec produced an LVAD, the HeartMate XVE, for use in "Destination Therapy." Destination Therapy ("DT") is designed for patients with end-stage congestive heart failure who are ineligible for heart transplantation. It involves the permanent implantation of an LVAD. Thoratec's Heartmate XVE is currently the only device approved for DT by the Food and Drug Administration ("FDA").

A clinical trial conducted from May 1998 through June 2001 included, among other treatments for congestive heart failure, a Thoratec HeartMate LVAD device. *Id.* at 23. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure

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[1] The court summarizes the facts from the complaint, assuming them to be true for the purpose of this motion. *Gompper v. VISX, Inc.*, 298 F.3d 893, 896 (9th Cir. 2002) ("On a motion to dismiss, the reviewing court must accept plaintiff's allegations as true and construe them in the light most favorable to the plaintiff.").

("REMATCH") trial included Thoratec's HeartMate SNAP-VE. Defs. Request for Judicial Notice ("RJN"), Ex. C (Eric A. Rose *et al*, *Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure*, 345 NEW ENG. J. MED. 1435, 1436 (Nov. 15, 2001)). Plaintiffs allege that the trial revealed serious problems with the use of the HeartMate LVAD device for DT, including device failure and high infection and mortality rates. Compl. ¶¶ 33-35.

The FDA granted "pre-market approval" for Thoratec's HeartMate SNAP-VE for DT on November 6, 2002. *Id.*, Ex. A at 4. In April 2003, the FDA granted supplemental approval to the HeartMate XVE for DT. In October 2003, the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program and assists the administration of Medicaid, approved a limited reimbursement for LVAD therapy. Compl. ¶ 25. The CMS reimbursement guidelines required, *inter alia*, that implantation be done at an approved transplant facility that had performed at least 15 LVAD implantations between January 1, 2001 and September 30, 2003. *Id.* There was also a list of medical requirements for eligibility for reimbursement including that the patient was ineligible for a heart transplant, had failed to respond to medical management, and had limited function with peak oxygen consumption. *Id.*

In April 2004, Blue Cross and Blue Shield Association issued a report entitled "Special Report: Cost-Effectiveness of Left-Ventricular Assist Devices as Destination Therapy for End-Stage Heart Failure." The report concluded that "[t]he baseline cost-effectiveness analysis . . . showed that the use of LVADs leads to an increase in cost of $802,700 to gain 1 [Quality of Life Year] compared with optimal medical management." Compl., Ex. A at 26. Thereafter, starting on April 20, 2004, Thoratec's stock began trading under $12 per share. Compl. ¶ 6.

Grossman is Thoratec's President, CEO, and a member of the Board of Directors. *Id.* ¶ 13. Boylston was a Senior Vice President and Thoratec's CFO.[2] *Id.* ¶ 14. On April 27, 2004, Thoratec issued a press release reporting first-quarter 2004 ("Q1 2004") results. That same day, Grossman and Boylston, along with Nelson, the President of Thoratec's Cardiovascular Division, conducted an earnings release conference call. *Id.* ¶ 42. Grossman and Boylston announced Thoratec's product

[2] Boylston resigned from Thoratec in December 2004 and is currently a consultant at Thoratec.

sales, taxed cash earnings, and net income for Q1 2004. They elaborated that sales of heart assist devices benefitted from Q1 2004 being the first full quarter in which Thoratec had both DT approval and the coverage by Medicare announced in October 2003, stating that 42 HeartMate devices were implanted in Q1 2004, a number roughly equal to the number of DT implants for all of 2003. *Id.* ¶ 42.

Grossman reiterated guidance for 2004 that had been provided in two prior calls. Thoratec projected revenues of between $190 and $200 million (an increase of 27 to 33 percent over 2003). It projected that 300 to 500 DT units would be implanted in FY 2004 and that revenue guidance was based on achieving the midpoint of that projection of 400 DT units. *Id.* Grossman also stated that he expected gross margin to stay in the "59-60 percent kind of range for the next few quarters." *Id.*

In addition, Nelson discussed Thoratec's DT sales market program extensively. *Id.* He discussed Thoratec's Heart Hope program, a collaborative effort between Thoratec and "leading heart centers committed to advancing clinical, educational, and economic outcomes of Destination Therapy" that was "just beginning to have an impact in the marketplace." Compl. Ex. E. Of the 67 CMS-approved DT therapy centers, approximately 20 were participants in Thoratec's Heart Hope program. Compl. ¶ 45(c).

Following the April 2004 conference call, Thoratec's stock price rose 10% in one day, from below $12 on April 27, 2004 to $13.20 per share on April 28, 2004. Compl. ¶ 43. On May 13, 2004, Thoratec included these revenue projections in its Form 10-Q filing for Q2 2004. *Id.* ¶ 49, Ex. H.

On May 11, 2004, Thoratec issued a press release stating that CMS had issued a proposed rule that would change the diagnosis-related group under which reimbursements were assessed, potentially resulting in increased reimbursement of 30% for VADs, from $96,000 to $125,000. RJN, Ex. B. Thoratec reportedly characterized this proposed rule "as a boon for patients opting for its HeartMate XVE LVAS device." Compl. ¶ 47, Ex. G (Andrew Wallmeyer, *Thoratec Comments On CMS Proposal Regarding VAD Reimbursement*, Dow Jones Newswires, May 11, 2004). Following this announcement, Thoratec's stock closed at $14.99 per share, a 15.4% increase over the May 10, 2004 close. *Id.* ¶ 47.

On May 17, 2004, four days after submitting its Form 10-Q filing, Thoratec announced a private placement of $125 million in senior subordinated convertible notes. Compl. ¶¶ 51-53. It announced it had sold a total of $143.7 million in notes on June 8, 2004 and used $60 million of the proceeds to repurchase shares of its common stock. *Id.* ¶ 54. Three weeks later, on June 29, 2004, defendants announced that Thoratec would not sell 400 DT units in 2004 and cut its sales projection to 200 units. *Id.* ¶ 57, 59, 60, Exs. M-O. On June 30, 2004, Thoratec stock lost over 25% of its value, or $3.68 per share, dropping from a per-share price of $14.42 to $10.74. *Id.* ¶ 62.

The first of these consolidated cases was filed August 3, 2004.

On December 2, 2004, Thoratec announced that, based on the first two months of Q4 2004, its DT implants were "roughly equivalent to that of each of the first three quarters of the year," ranging between 34 to 42 per quarter. *Id.* ¶ 63, Ex. P. Boylston resigned on December 17, 2004. *Id.* ¶ 65. On January 10, 2005, Thoratec reported that it has failed to meet its revised projection. It announced that it had sold 171 devices in FY 2004, missing its restated estimate by 29 units, or 15%. *Id.* ¶ 66.

II. ANALYSIS

A. Documents Properly Before the Court

When considering a motion to dismiss, the court is generally confined to consideration of the allegations in the pleadings. Fed. R. Civ. P. 12(b)(6). However, when the complaint is accompanied by attached documents, such documents are deemed part of the complaint and may be considered in evaluating the merits of a Rule 12(b)(6) motion. *Durning v. First Boston Corp.*, 815 F.2d 1265, 1267 (9th Cir.), *cert. denied sub. nom. Wyo. Cmty. Dev. Auth. v. Durning*, 484 U.S. 944 (1987). The court may also consider documents incorporated by reference, *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 773 (2d Cir. 1991); *see also Townsend v. Columbia Operations*, 667 F.2d 844, 848 (9th Cir. 1982), and documents "whose contents are alleged in the complaint and whose authenticity no party questions," *Branch v. Tunnell*, 14 F.3d 449, 453-54 (9th Cir. 1994), *cert. denied*, 114 S.Ct. 2704 (1994); *see also In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1405 (9th Cir. 1996).

Defendants request judicial notice of five documents: (1) Thoratec's Form 10-K Report for fiscal year ended January 3, 2004; (2) a press release issued by Thoratec on May 11, 2004, (3) a

November 2001 article from the *New England Journal of Medicine* entitled "Long-Term Use of a Left Ventricular Assist Device for End Stage Heart Failure" publishing the results of the REMATCH trial; (4) the market price of Thoratec's common stock during November 2001; and (5) premarket approval orders for the HeartMate LVAS issued by the FDA on various dates. Plaintiffs do not dispute that judicial notice is proper with respect to the Form 10-K Report or the press release, however, they contend that the remaining items are not properly subject to judicial notice. Defendants, on the other hand, argue that the court may "examine the other information that was publicly available to reasonable investors at the time the defendant made statements plaintiffs alleged were fraudulent, including documents or articles cited in the complaint, SEC filings, press releases, stock price tables, and other material on which plaintiffs' allegations necessarily rely." *In re First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 883 (W.D.N.C. 2001).

The court finds it appropriate to take judicial notice of the *New England Journal of Medicine* article regarding the REMATCH trial results to the extent that defendants rely upon it for the date it was published. The court takes judicial notice of the publication date, but, as set forth below, the court does not consider defendant's "truth on the market" defense at the present stage of litigation. The court may also rely on the article to the extent that plaintiff's allegations rely upon the REMATCH trial results. The complaint refers extensively to the REMATCH trial results but plaintiff attaches only articles and other documents referencing the trial results. Thus, the court may take judicial notice of the *New England Journal* article contents in order to establish the sufficiency of the allegations. *See Parrino v. FHP*, Inc., 146 F.3d 699, 706 (9th Cir. 1998); *see also Wietschner v. Monterey Pasta Co.*, 294 F. Supp. 2d 1102, 1110 (N.D. Cal. 2003) ("Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support plaintiff's claim.").

Plaintiff's complaint does not necessarily rely upon either Thoratec's stock price around the announcement of the REMATCH trial results or the FDA premarket approval orders. Defendants assert that the stock prices around the REMATCH results are subject to judicial notice in support of

a "truth on the market" defense. However, "a 'truth-on-the-market' defense is available in principle . . . but not at the pleading stage." *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 734 (7th Cir. 2004). Thus, the stock values in 2001 are not critical at this stage of the litigation. Likewise, plaintiff does not contest that the Thoratec devices have received FDA approval.[3] Defendants seek to use the contents of these FDA documents to establish that the HeartMate XVE incorporated improvements addressing concerns raised by the REMATCH trial data and that this information was reflected in the stock price. This would constitute an impermissible use of a judicially noticed fact. Accordingly, the court declines to take judicial notice of the FDA premarket approval orders.

B. Pleading Standards

"In an effort to deter abusive and frivolous securities fraud claims, Congress enacted the PSLRA, which amended the 1934 Act and raised the pleading standards for private securities fraud claims." *No. 84 Employer-Teamster v. America West Holding* ("*America West*"), 320 F.3d 920, 931 (9th Cir. 2003) (citing *In re Silicon Graphics Inc. Sec. Litig*. ("*Silicon Graphics*"), 183 F.3d 970, 973 (9th Cir. 1999)). The Private Securities Litigation Reform Act ("PSLRA") requires that a complaint plead with particularity both falsity and scienter. *America West*, 320 F.3d at 931. If a plaintiff fails to plead either the alleged misleading statements or scienter with particularity, his or her complaint must be dismissed. *See America West*, 320 F.3d at 931-32; 15 U.S.C. § 78u-4(b)(3)(A).

First, where plaintiff alleges that the defendant either (1) made an untrue statement of material fact or (2) omitted to state a material fact necessary to make statements made not misleading, the PSLRA requires

> the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1); *America West*, 320 F.3d at 931. Second, with regard to pleading scienter,

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[3] The Court may take judicial notice of the FDA preapproval notices as a matter of public record. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir.1993) (noting that court may take judicial notice of public records on a Rule 12(b)(6) motion); *Lamers Dairy Inc. v. USDA*, 379 F.3d 466, 471 n.8 (7th Cir. 2004) ("This court may take judicial notice of reports of administrative bodies."); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 745 n. 2 (E.D. Pa. 2003) (taking judicial notice of FDA report posted on the official FDA website).

the PSLRA provides the complaint shall "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

In the Ninth Circuit, these dual pleading requirements of sections 78u-4(b)(1) and (b)(2) are incorporated into a single inquiry, "because falsity and scienter are generally inferred from the same set of facts." *In re Read-Rite Corp.*, 335 F.3d 843, 846 (9th Cir. 2003). Thus, to determine whether a private securities fraud complaint survives a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must ascertain whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or with deliberate recklessness made false or misleading statements to investors. *Id.* at 846; *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001). Where pleadings "taken as a whole, [] do not raise a 'strong inference' that misleading statements were knowingly or [with] deliberate recklessness made to investors, a private securities fraud complaint is properly dismissed under Rule 12(b)(6)." *Ronconi*, 253 F.3d at 429; *see also Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 (9th Cir. 2002).

C. Safe Harbor

Defendants contend that a majority of false or misleading statements alleged by plaintiff are forward-looking statements subject to the PSLRA's safe harbor provision. A forward-looking statement is defined as a statement containing a projection of revenues, income, or earnings per share, management's plans or objectives for future operations, or a prediction of future economic performance. 15 U.S.C. § 78u-5(*i*)(1)(A)-(C). Under the safe harbor provision of the PSLRA, a company may not be liable for forward-looking statements if they are identified as such and accompanied by specific, meaningful cautions. 15 U.S.C. § 78u-5(c). For safe harbor protection under the PSLRA to apply, the forward-looking statements must either be: (1) accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially;" or (2) must not be made with actual knowledge of falsity. *See* 15 U.S.C. § 78u-5(c)(1)(A); 15 U.S.C. § 78u-4(b)(1)-(2).

The safe harbor requires that the cautionary language mention "important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 77z-2(c)(1)(A)(i). Plaintiff contends that defendants' forward-looking statements were not

accompanied by the requisite cautionary language.[4] Defendants, on the other hand, demonstrate based on plaintiff's pleadings that Thoratec's March 17, 2004 Form 10-K referenced at the beginning of the conference call and other relevant document warned of precisely the risks plaintiff complains of: (a) that third-party payors would "fail to provide appropriate levels of reimbursement" (RJN, Ex. A at 19); (b) that the market was constrained by the number of hospitals approved by CMS for DT, patient and physician acceptance of DT, and actual clinical results (*id.* at 20); (c) that relative cost and efficacy of alternative therapies might limit the use of DT (*id.*); and (d) that other "economic, psychological, ethical and other concerns" may limit acceptance of ventricular assist products (*id*. at 21). The court agrees that these stated risks track the contents of the forward-looking statements of which plaintiff complains.

Relying on *Asher v. Baxter Int'l, Inc.*, 377 F.3d 727 (7th Cir. 2004), plaintiff argues that the issue of whether defendants' cautionary statements were adequate is a question of fact that cannot be decided on a motion to dismiss. However, the Ninth Circuit has stated otherwise: "The bespeaks caution doctrine provides a mechanism by which a court can rule as a matter of law (typically in a motion to dismiss for failure to state a cause of action or a motion for summary judgment) that defendants' forward-looking representations contained enough cautionary language or risk disclosure to protect the defendant against claims of securities fraud." *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1413 (9th Cir. 1994). The PSLRA safe harbor is a statutory form of the bespeaks caution doctrine. *Employers Teamsters Local Nos. 175 & 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125, 1132 (9th Cir. 2004). Thus, courts may rule as a matter of law, where appropriate, that cautionary language was sufficient under the first prong of the safe harbor provision.

The court in *Baxter* recognized that the "PSLRA does not require the most helpful caution" so long as the caution is enough to identify "important factors that could cause actual results to differ

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[4] The PSLRA does not require that the cautions physically accompany oral statements. If other requirements are met, an oral statement may specify that "additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statement is contained in a readily available written document." 15 U.S.C. § 78u-5(c)(2)(B)(i); *Employers Teamsters Local Nos. 175 & 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125, 1133 (9th Cir. 2004). Plaintiff does not dispute that the caution may be in a written document, rather he questions the sufficiency of those cautions.

materially from those in the forward-looking statement." 377 F.3d at 733. "The statute calls for issuers to reveal the 'important factors' but not to attach probabilities to each potential bad outcome, or to reveal in detail what could go wrong . . ." *Id.; see also In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 822 (N.D. Cal. 2004). As here, where the important factors identified in conjunction with the forward-looking statement are precisely those that the plaintiff contends caused the actual results to differ materially, it is difficult to see how the cautionary language could be inadequate. Thus, the inquiry must then move to the second test: whether defendants had actual knowledge of the falsity of their forward-looking statements. 15 U.S.C. § 78u-4(b)(1)-(2).

D. False or Misleading Statements

For purposes of their motion to dismiss, defendants grouped the alleged false or misleading statements into two categories: statements of present or historical fact and forward-looking statements.

1. Statements of Present or Historical Fact

Defendants argue that a majority of the purportedly false or misleading statements alleged by plaintiff were forward-looking statements subject to safe harbor protection under the PSLRA. However, as to the statements of present or historical fact alleged to be false or misleading, defendants contend that plaintiff failed to allege facts to support his allegations. Specifically, defendants challenge the following statements from the April 27, 2004 press release and conference call: (1) "[w]e feel we are off to a good start," (2) "[o]ur results for the quarter reflect solid growth," (3) "[w]e are very pleased with the response to Heart Hope to date," (4) "[t]he response from attendees, who are thought leaders, was very positive and they came away with even a higher level of enthusiasm for the [DT] opportunity", (5) "there is a tremendous amount of enthusiasm in our organization and the marketplace right now", and (6) "we are more certain than ever that [DT] is going to be a very significant market." Compl. ¶¶ 41, 42. Defendants also challenge plaintiff's allegations regarding the falsity of the following statement from a June 29, 2004 Knobias press report: "We remain very encouraged by the level of interest and activity of our customers and continue to be optimistic that Destination Therapy activity will accelerate later in the year, and especially in 2005." *Id.* ¶ 60, Ex. O.

Plaintiff does not appear to address defendants' challenge to the adequacy of his pleadings regarding the falsity of these statements of present or historical fact.

2. Forward-looking statements

Defendants also argue that the following forward-looking statements were subject to the PSLRA safe harbor provisions: (1) Thoratec's sales projections, (2) its 2004 revenue projections, (3) general statements of optimism concerning its DT devices, (4) its predicted gross margins, (5) the future costs of DT, (6) factors driving future growth in DT, (7) assumptions underlying the sales and financial projections, and (8) predicted CMS reimbursement rate. Plaintiff does not dispute that these are forward-looking statements as defined by the PSLRA. 15 U.S.C. § 78u-5(i)(1). Plaintiff does, however, argue that the statements are not entitled to safe harbor protection, contending, first, that the statements were not accompanied by meaningful cautionary statements and, second, that the statements were made with actual knowledge of their falsity. As set forth above, the court finds that the cautionary statements provided are sufficient as a matter of law with respect to the forward-looking statements pleaded.

Regarding actual knowledge of falsity, first, the court notes that plaintiff did not address defendants' arguments that its prediction about competition for the HeartMate XVE was false or misleading when made. As support for his contention that defendants' positive statements about the potential market for the HeartMate XVS were knowingly false, plaintiff alleges that Thoratec faces "substantial competition" from World Heart Corporation's Novacor Left-Ventrical Assist System ("Novacor LVAS"). In particular, plaintiff notes the commencement of a clinical trial directly comparing the HeartMate XVE to the Novacor LVAS, the RELIANT trial. However, the complaint also notes that the RELIANT population trial began in February 2004 and does not otherwise plead that defendants had access to the trial results at the time the allegedly false statements were made in April 2004. Compl. ¶ 37.

As a result it would appear, as defendants contend, that plaintiff only sought in his papers to support the falsity of the following statements: (1) Thoratec's April 27, 2004 affirmance of its November 2003 projection of 300-500 implants in 2004; (2) the June 29, 2004 restated projection of 200 implants in 2004; and (3) Thoratec's revenue projections of $190-$200 million based on meeting

the midpoint of the implant projection. Thus, as all allegedly false or misleading statements derive from the alleged falsity of defendants' projections regarding the number of DT implantations for 2004, the court restricts its analysis of falsity and scienter to this issue.

a. Market Size Projection

As evidence that defendants had actual knowledge that their implant projection of 300-500 was false, plaintiff claims that Thoratec falsely "estimated that as many as 100,000 patients per year in the United States could be helped by their new DT treatment option" while knowing that the real number was closer to 200. Compl. ¶ 39(a). Defendants argue, and the court agrees, that plaintiff's allegation is itself misrepresentative of what Thoratec actually stated. Thoratec stated "we estimate the market penetration for this indication could be between 5,000 and 15,000 patients annually using current approved to technology and up to 100,000 patients annually in the United States alone as we introduce new technologies that increase the life of our VAD and improve the life of our VAD and improve the outcome of procedures." RJN, Ex. A. This statement does not indicate that Thoratec misrepresented that the HeartMate XVE could be implanted into 100,000 patients annually.[5]

Plaintiff's contention that by 2004 certain experts had estimated market size for LVAD implants at 200 over two years likewise does not allege with particularity that defendants had actual knowledge that their market size projection of 5,000 to 15,000 patients was false. Aside from a WebMD article published in August 2004, after both the April 27, 2004 projection and June 29, 2004 revised projection, plaintiff fails to identify any experts who held such an opinion or that defendants had knowledge of such opinions, if any existed.

b. Prohibitive Costs

Defendants contend that none of plaintiff's allegations regarding the costs of LVAD implantation is true and, even if true, none would suggest that defendants had actual knowledge their projections were false. The defendants argue that, even assuming that they did not reveal that the

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[5] One of the articles attached to the complaint supports defendants' estimate that 5,000 to 15,000 patients would be viable candidates for LVAD DT devices. *See* Compl., Ex. C (Mehmet C. Oz *et al*, *Left Ventricular Assist Devices as Permanent Heart Failure Therapy: The Price of Progress*, 238 ANNALS SURG. 577, 582 (October 2003) (stating that "of the estimated 60,000 patients who could benefit from cardiac transplantation each year, we conjecture approximately 20% [*i.e.*, 12,000 patients] would be candidates for long-term LVAD therapy at present")).

costs of DT exceeded the even the projected increased reimbursement benefit, plaintiff has failed to plead facts that show the cost of LVAD DT implantation limited the number of implants to be performed. Defendants contend that plaintiff has failed to allege that the cost of DT implantation in 2004 was equal to or greater than the cost of implantation during the REMATCH trial and, accordingly, that plaintiff's allegations related to the costs of DT based on the REMATCH trial have no bearing on the costs of the HeartMate XVE. This argument is unavailing, as the inference favoring plaintiff, that the implantation cost remained the same or increased between the REMATCH trial and the announcement, is a reasonable one. However, plaintiff lists among the costs of LVAD implantation additional expenses such as hospitalization costs associated with the 88 median days of hospitalization known to be required after LVAD implantation. Compl. ¶ 44(c). Even assuming the hospitalization costs of LVAD implantation exceed the projected reimbursement benefit for implantation of the LVAD device, plaintiff has not alleged facts showing that the additional costs would result, as he conclusorily claims, that "cardiac transplant and CHF centers did not promote DT due to the fact that they would generally lose money." *Id.* Thus, as pleaded, the amount of reimbursement benefit as compared with the total cost of LVAD DT does not support a strong inference that defendants' statements were made with scienter.

c. Implantation Rate

Plaintiff contends that the rate of implantation in 2004 at the date of the April 27, 2004 press release clearly demonstrates that Thoratec's projection of 300-500 implants for fiscal year 2004 was unachievable. Defendants disclosed that there had been 42 DT implantations of the HeartMate XVE in Q1 2004. In the following quarter, only 34 placements of the HeartMate XVE were made.

The April 27, 2004 announcement was made one month, or one-third of the way, into Q2 2004. Plaintiff contends that, even assuming all Q1 and Q2 implants had been made by the time of the April 27 announcement, Thoratec's midpoint projection of 400 units could not have been met. Plaintiff asserts that a projection of 400 units requires a steady sales rate throughout the year, thus, Thoratec would have had to sell 100 units per quarter to meet its projection. Since it only sold 42 units the first quarter, Thoratec would have had to sell approximately 119 devices each remaining quarter to meet its 400 implant projection by the end of the year.

Defendants, on the other hand, assert that nothing in their projection indicated that the sales projection would be equally balanced throughout the remaining quarters of 2004. Instead, they contend that, given (1) the increase in the number of implants from FY 2003 to Q1 2004 placements, and (2) Thoratec's repeated assertion that sales would be back-ended into the later quarters of 2004, it is reasonable to infer that defendants projections were based on ramping sales throughout the year. Based on such an assumption, a 400-unit placement projection would have been achievable: Q1 = 42; Q2 = 80; Q3 = 120; Q4 = 160. Therefore, anticipation of such increasing numbers may have seemed justified at the time, given that the 42 units implanted in Q1 2004 equaled the sales in all of 2003.

In a motion to dismiss under the PSLRA, "when determining whether plaintiffs have shown a strong inference of scienter, the court must consider *all* reasonable inferences to be drawn from the allegations, including inferences unfavorable to the plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002); *see also Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004). When weighing the competing inferences set forth above, the court finds that the inference that defendants had a good-faith basis for their projection based upon anticipated late-year sales at least as plausible as plaintiff's conclusion that defendants acted with scienter. Without more, plaintiff has failed to show a strong inference that either the April 27, 2004 projection or the June 29, 2004 restated projection was either false or made with actual knowledge that the projected number of implants was unachievable when made.[6]

d. Opinions of the Medical Community

Plaintiff contends that "[i]nvestigation and consultation with doctors in the medical field regarding DT and investigations of transplant centers . . . revealed that by at least 2004, the HeartMate LVAD device would not have the market share defendants claim." While seeming to plead with particularity that defendants were aware of the existence of information between April

[6] Plaintiff also argues that Thoratec's sales cycle as acknowledged in their 10-K Form was nine to eighteen months and that, as a result, Thoratec would have known by April 27, 2004 that its implantation projections were false. Defendants point out that the period set forth in the 10-K Form is nine to eighteen months from "initial contact with the cardiac surgeon until purchase" (RJN, Ex. A at 12) and that this number does not reflect the number of DT implants that would be performed by existing DT centers familiar with the HeartMate device.

27, 2004 and June 29, 2004—when the statements regarding the potential market share for LVADs for DT were made—closer inspection reveals that plaintiff has failed to plead that the information was available to defendants. While plaintiff lists the transplant centers participating in the "consultation and investigation," he does not provide any details as to where the adverse information may have been compiled or how defendants may have had access to it.

Furthermore, plaintiff alleges that cardiologists and patients were shying away from DT due to medical problems associated with DT complications and the costliness of the DT option. While plaintiff presents allegations that there were problems with the device and that it was an expensive option, particularly as compared with medical management, he identifies no medical opinions or reports that demonstrate that these factors were causing either physicians or patients to forego the option.[7]

e. Truth on the Market

Defendants argue that their truth-on-the-market defense demonstrates that they did not have actual knowledge of falsity regarding their forward-looking statements, requiring the court to dismiss plaintiff's complaint. As set forth above, courts generally may not dismiss a complaint on the basis of a truth-on-the-market defense to a fraud-on-the-market theory. *Cf. Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000) ("The truth-on-the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality."); *Provenz v. Miller*, 102 F.3d 1478, 1492-93 (9th Cir. 1996) ("Before the 'truth-on-the-market' doctrine can be applied, the defendants must prove that the information that was withheld or misrepresented was 'transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by insider's one-sided representations.'") (citing *Kaplan v. Rose*, 49 F.3d 1363, 1376 (9th Cir. 1994)). Thus, the

[7] While defendants attempt to demonstrate in their motion to dismiss that the medical problems present in the devices used in the REMATCH trial had been resolved in the HeartMate XVE, this attempt presents a factual question that the court must resolve in plaintiff's favor. The inferences that could be drawn from the evidence defendants present (such as the FDA premarket approval sheets showing approval of an improvement to the inflow valve of the HeartMate device) do not suffice to overcome the inference that the problems with use of LVADs in DT persisted.

court finds defendants' arguments that the information was already available to the public to be an inappropriate basis for finding an insufficient pleading of scienter and falsity.

C. Additional Scienter Allegations

As set forth above, the PSLRA provides that the complaint shall "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). In the Ninth Circuit, plaintiffs must allege facts sufficient to create an inference of "deliberate or conscious recklessness." *America West*, 320 F.3d at 931.[8] "In order to show a strong inference of deliberate recklessness, plaintiffs must state facts that come closer to demonstrating intent, as opposed to mere motive and opportunity." *In re Silicon Graphics*, 183 F.3d at 974. Here, plaintiff additionally seeks to satisfy the scienter pleading requirement by alleging that defendants were motivated to make misleading or fraudulent statements to keep the Thoratec's stock price high for Thoratec's May 2004 private placement offering in order to recoup substantial cash losses from marketing DT.

Plaintiff contends that defendants intended to fraudulently inflate Thoratec's stock price. Less than a week after Thoratec filed its 10-Q Form for Q1 2004 containing the allegedly false material, it announced it was making a $125 million note offering. Defendants had spent $4 million to launch DT programs in Q1 2004, but had only made $1.3 million in the same period. Plaintiff contends that Thoratec's need to raise capital to cover this shortfall demonstrates a strong motivation to keep Thoratec's stock price high. The higher the stock price, the more attractive the offered notes would be to investors.

The court concludes that plaintiff has failed to allege sufficient particularized facts to support a strong inference that defendants intended to commit fraud with respect to the private placement offering. Plaintiff's complaint quotes the announcement as stating that Thoratec intended to use the proceeds of the private placement offering to repurchase its stock. Inflating the price of the stock only to repurchase it at the inflated price does not give rise to a strong inference that defendants had

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[8] Or, as set forth above in the safe harbor discussion, where the challenged act constitutes a forward-looking statement, "actual knowledge . . . that the statement was false or misleading." *Id.*

a strong motive to fraudulently prop up Thoratec's stock price.[9] Plaintiff alleges that defendants were motivated to commit fraud to preserve their salaries and keep their jobs. However, he alleges no facts to support a strong inference that defendants' jobs were in jeopardy as a result of the $4 million expenditure in light of the $1.3 million income. Nor does he explain why $143 million would have been required to cover a $2.7 million net expenditure on marketing DT. Absent a particular motive, "a generalized motive, one which could be imputed to any publicly-owned, for-profit endeavor, is not sufficiently concrete for purposes of inferring scienter." *Kalnit v. Eichler*, 264 F.3d 131, 140 (2d Cir. 2001).

Finally, the court considers whether the totality of plaintiff's scienter allegations, even though individually lacking, are sufficient to create a strong inference that defendants acted with deliberate or conscious recklessness, if not actual knowledge. *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002). Here, absent pleadings sufficiently particular to demonstrate actual knowledge of falsity, the allegations of motive are simply too generalized to create a strong inference that defendants acted knowingly or with deliberate recklessness.

D. Controlling Person Liability

Section 20(a) provides joint and several liability for controlling persons who aid and abet securities violations. 15 U.S.C. § 78t(a). To prove a prima facie case under section 20(a), a plaintiff must prove: "(1) 'a primary violation of the federal securities law' and (2) 'that the defendant exercised actual power or control over the primary violator.'" *America West*, 320 F.3d at 945 (quoting *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000)).

"To be liable under section 20(a), the defendants must be liable under another section of the Exchange Act." *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 978 (9th Cir. 1999). Defendants contend plaintiff's section 20(a) claims must be dismissed because plaintiff's complaint fails to satisfy the pleading requirements for the asserted section 10(b) and 10b-5 violations—without a primary violation of federal securities law, plaintiff would be unable to make out a prima

[9] As plaintiff argues, neither does a stock repurchase necessarily negate scienter. *See America West*, 320 F.3d at 928-38 (holding that plaintiffs had sufficiently pled scienter after considering a stock repurchase among the factors).

facie case under section 20(a). As set forth above, plaintiff has failed to plead primary securities law violations by defendants. Therefore, plaintiff's section 20(a) claim must be dismissed.

E. Leave to Amend

Leave to amend is to be freely granted when justice so requires. *See* Fed. R. Civ. P. 15(a). "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital v. Aspeon Inc.*, 316 F.3d 1048, 1053 (9th Cir. 2003) (error to refuse leave to amend in a securities fraud case to allow plaintiff to plead scienter).

It is possible that plaintiff could remedy the pleading defects in an amended complaint by demonstrating that defendants the requisite scienter at the time the statements were made. *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (leave to amend should be granted unless the district court "determines that the pleading could not possibly be cured by the allegation of other facts"). Accordingly, the court grants dismissal without prejudice in order to allow plaintiff the opportunity to attempt to remedy the pleading defects if he so chooses.

III. ORDER

For the foregoing reasons, the court finds the complaint fails to adequately allege the falsity of the challenged statements and defendants' scienter with the requisite particularity. Therefore, the court grants without prejudice defendants' motion to dismiss the complaint for failure to state a claim. Plaintiffs shall have 30 days from the date of this order to file an amended complaint.

DATED: 5/10/06

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge

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Dated: 5/11/2006

Chambers of Judge Whyte